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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/646,748	12/11/2000	Julio Boza	112701 036	7778

7590 01/10/2006

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EXAMINER	
MOHAMED, ABDEL A	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 01/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/646,748	BOZA, JULIO	
	Examiner	Art Unit	
	Abdel A. Mohamed	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 October 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/07/05, 12/09/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

REASSIGNMENT AFFECTING APPLICATION LOCATION

1. The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1654.

ACKNOWLEDGMENT OF AMENDMENT, REMARKS, STAUS OF THE APPLICATION AND CLAIMS

2. The amendment and remarks filed 10/28/05 and the information disclosure statement (IDS) and Form PTO-1449 filed 11/17/05 and 12/09/05 are acknowledged, entered and considered. In view of Applicant's request, claims 1-3 have been amended. Claims 1-16 are now pending in the application. The rejection under 35 U.S.C. 102(b) over the prior art of record is maintained for the reasons of record.

ARGUMENTS ARE NOT PERSUASIVE

CLAIM REJECTIONS-35 U.S.C. § 102(b)

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) The invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-16 remain rejected under 35 U.S.C. 102(b) as being anticipated by Ballevre et al (U.S. Patent No. 5,849,335).

Applicant's arguments filed 10/28/05 have been fully considered but they are not persuasive. Applicant has argued that the reference of Ballevre et al fails to disclose or suggest a nutritional composition including a protein source having at least 80% by weight of a whey protein and/or simulated whey protein as required by the present claims. Instead Ballevre et al disclose the carob protein comprises about 40% to about 100% by weight of the protein source of its nutritional composition. As a result the product of Ballevre cannot anticipate the present claims is unpersuasive.

Contrary to Applicant's arguments, as discussed in the previous Office action, Ballevre et al disclose a nutritional composition comprising a protein source including whey protein and a protein mixture having the amino acid profile of whey protein which is administered to stressed patients to increase the plasma glutamine concentration, or administered as nutritional support for increasing muscle glutamine concentration in athletes after exercise, or administered to patients suffering from injured or diseased intestines or to maintain the physiological functions of the intestines particularly in under-developed intestines (e.g., a pre-term infant or babies) as disclosed on the abstract; col. 1, lines 44-50; col. 3, lines 1-25; col. 6, lines 13-38; claims 24, 26-28 and 30. Thus, clearly meeting the limitations of claims 1-4.

On col. 4, the prior art discloses the use of nutritional composition wherein the whey protein is hydrolyzed whey protein, the protein source provides about 10% to about 30% of the energy of the nutritional composition, the nutritional composition further includes a lipid source which provides about 20% to about 40% of the energy of the nutritional composition and the lipid source comprises a mixture of medium chain

and long chain fatty acids, and as such meet the limitations of claims 5, 6, 8, 9, 11, 12, 14 and 15. The reference also discloses a nutritional composition which further includes a carbohydrate source which provide about 35% to about 60% of the energy of the nutritional composition and as such meet the limitations of claim 10, 13 and 16 (See e.g., col. 2, lines 46-64; col. 4, lines 4-56 and Examples 2-4).

In regard to the percentages of the whey protein, the percentages claimed is inherent in the casein of milk which clearly reads on the limitation of **approximately** 80% to about 90% by weight of casein, and further overlaps with the disclosed amount of about 10 to 30% of mixtures of whey and casein because **approximately** is a relative term which encompass the recited ranges disclosed by the prior art. Thus, the reference clearly discloses the administration of nutritional composition, which contains whey protein (or a protein mixture which stimulates its acid profile) as a protein source for the same purposes (i.e., for increasing glutamine levels in plasma or muscle of a stressed patient, pre-term baby or athletes). Therefore, as the whey protein hydrolysate comprises glutamine and it is used for nutritional purposes (i.e., a metabolic process), which is a mechanism wherein the sum total of chemical and physical processes within the body related to release of energy by the breakdown of chemical fuel and the use of that energy by the cells for their own work. Thus, clearly showing the known principles of physiology that naturally occurs after intake of food or meal that increases plasma glutamine concentration in mammals, increases muscle glutamine concentration in mammal and provides treatment to patients suffering from injured, diseased or under-developed intestines.

With respect to Applicant's argument that Ballevre is concerned with a glutamine rich nutritional composition used for glutamine supplemented diets and cites col. 2, lines 27-30. This teaches away from the present claims, which are directed to nutritional composition having low glutamine concentrations is noted. However, the limitations Applicant argued with (i.e., nutritional compositions having low glutamine concentration) are not recited in the rejected claims. Nevertheless, the claims are interpreted in light of the specification limitations from the specification are not read into claims. See *In re Geuns*, 988 F.2nd 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Thus, Applicant's arguments are not commensurate to the scope of the claims.

Further, the claims are broader than argued by Applicant because claims 1-16 are directed to methods for increasing glutamine by using whey protein or a protein mixture administered to a patient to increase plasma glutamine concentration in stressed mammal (claim 1), to increase muscle glutamine concentration in mammal (claim 2), to use as nutritional/therapeutic composition to a mammal suffering from injured, diseased or under-developed intestines (claim 3), wherein the mammal is a pre-term infant having an under-developed intestines (claim 4), wherein the protein is hydrolyzed (claims 5 and 6) and having the various molecular weights recited in claim 7, wherein the protein source provide energy of the nutritional composition thereof (claims 8, 11 and 14), wherein the nutritional composition further includes a lipid source (claims 9, 12 and 15) and wherein the nutritional composition includes carbohydrate source (claims 10, 13 and 16). Therefore, the prior art discloses the invention substantially as

claimed, in the absence of evidence to the contrary the nutritional formulation and its use thereof as disclosed by the reference anticipate claims 1-16 as drafted.

ACTION IS FINAL

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

CONCLUSION AND FUTURE CORRESPONDANCE

5. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abdel A. Mohamed whose telephone number is (571) 272 0955. The examiner can normally be reached on First Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, CAMPELL BRUCE can be reached on (571) 272 0974. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JON WEBER
SUPERVISORY PATENT EXAMINER

Mohamed/AAM

January 6, 2006